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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,628	11/13/2001	Ronald L. Ream	112703-203	4209
29156	7590	08/26/2004		
BELL, BOYD & LLOYD LLC P. O. BOX 1135 CHICAGO, IL 60690-1135			EXAMINER HOWARD, SHARON LEE	
			ART UNIT 1615	PAPER NUMBER
DATE MAILED: 08/26/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/990,628	REAM ET AL.	
	Examiner	Art Unit	
	Sharon L. Howard	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The examiner acknowledges receipt of the petition for extension of time and remarks filed on 7/26/04.

Claims 9-26 are pending in this application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9,11-18,20-26 remain rejected under 35 U.S.C. 102(b) as being anticipated by Reed et al. (U.S. Patent No. 5,665,406).

Reed teaches a pellet chewing gum which is coated with one more coats of a polyol such as maltitol, lactitol and erythritol. According to the "Hack's Chemical Dictionary", Second Edition, page 349, erythritol is used medicinally as a vasodilator, and therefore, erythritol can be defined as a medicament. Reed teaches that the chewing gum includes a gum center and an outer coating. Reed teaches that the gum center constitutes from about 35 to about 90 weight percent of the chewing gum product. The gum center which is sugarless comprises xylitol, maltitol and/or sorbitol. The outer coating contains from about 50 to about 100 weight percent of two polyols. See abstract and column 5, lines 5-25. Reed also teaches that the coating may also contain from about 0.05 to about 0.3 weight percent of artificial sweeteners such as aspartame, acesulfame-K, saccharin and sucralose. See column 7, lines 52-55 and

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column 8, lines 1-6. The gum base contains from about 10 to about 50% by weight of the chewing gum center. See column 8, lines 50-59.

The reference clearly shows a chewing gum pellet which is coated with a polyol, having a sugarless gum center.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10,19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Reed ('406) in view of Khan et al. (U.S. Patent No. 5,656,296).

Reed is discussed above.

Reed does not teach the particular medicament.

However, Khan teaches drug delivery systems containing a core and a coating layer over the core, wherein the coated core comprises a core and a medicament. See

abstract. Khan teaches medicaments such as analgesics, anti-inflammatory agents, cardiovascular preparations, decongestants and vitamins and minerals. See column 3, lines 24-52. Khan teaches that the coating layer of the drug delivery system may also contain sweetening agents and active agents. See column 7, lines 1-6.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the particular medicament taught by Khan in the Reed reference, for the purpose of delivering a medicament to the outer layer.

Response to Arguments

Applicant's arguments filed 7/26/04 have been fully considered but they are not persuasive. Applicant argues that Khan ('296) fails to disclose or suggest a medicament in the coating. The medicament in the core is neither taught nor suggested by the cited references.

In response to applicant's arguments, the Reed et al. ('406) reference suggests the teachings of a medicament in the outer layer. Reed teaches that the outer coating contains from about 50 to 100 weight percent of a polyol such as erythritol (see abstract and col.5, lines 5-25). According to the "Hackh's Chemical Dictionary", Second Edition, (see page 349), erythritol is used medicinally as a vasodilator. It remains the position of the examiner that erythritol can be defined as a medicament.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

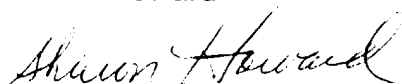
TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Howard whose telephone number is (571) 272-0596. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharon Howard



THURMAN K. PAGE
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